

REMARKS

Claims 1-4, 6-14, 16, 18-19, 25-26 and 37-42 are pending in this application, of which claims 4, 9, 14, 16, 26 and 40 are currently withdrawn from examination pursuant to a previous election, but are to be reinstated and allowed upon allowance of a respective generic (and any intervening) claim from which the respective withdrawn claim depends. Claims 5, 15, 17, 20-24, 27-36 are cancelled. Based on the following remarks, reconsideration and allowance of the application is respectfully requested.

Information Disclosure Statement

A supplemental information disclosure statement is submitted herewith, including additional office action of related US Patent Application S.N. 10/669,543. Applicant respectfully requests consideration of the documents cited in the information disclosure statement.

Claim Rejections - 35 U.S.C. §103

Claims 1-3, 6-8, 10-13, 18, 19, 25 and 37-42 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over U.S. Patent No. 5,853,418 ("Ken") in view of U.S. Patent No. 6,238,421 ("Gunther et al"), and in further view of U.S. Patent No. 6,280,457 ("Wallace") and still further view of U.S. Patent No. 6,024,724 ("Engelson"), a combination of four separate references. In particular, the Examiner has asserted that, in view of Gunther, in further view of Wallace and still in further view of Engelson, it would have been obvious to one skilled in the art to construct the coil device described in Ken, heating the coil of Ken with the external device of Gunther, provide a polymeric coating having bioactive agent per Wallace to the coil of Ken and still the coating being release upon

heating per Engelson to enhance the treatment of aneurysm. Applicant respectfully disagrees.

The Supreme Court has addressed the issue of obviousness in KSR International vs. Teleflex Inc., 550 U.S. ____ (2007), in which the Court reiterated the requirement that a rejection on “obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” (KSR at page 14 of the slip opinion), and further that a “fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning. (KSR at page 17 of the slip opinion). Also, while not specifically addressed by the Supreme Court in KSR, the prior art reference (or references when combined) must teach or suggest all the claim limitations (See MPEP §2143).

Independent claims 1, 37, and 42 each recite a first material which, if the device is detached from a delivery catheter and implanted at a treatment site, may be heated by application of energy transmitted by an energy emitting element located external to the patient, and a bioactive agent (claims 1 and 37) or second material (claim 42) which, if the device is detached from a delivery catheter and implanted at a treatment site, is released (claim 1) or activated (claim 37) or partially melt or fuse together (claim 42) from the device upon heating the device by application of energy transmitted by said external energy emitting element.

In contrast, Ken discloses a stretch-resisting member for a vaso-occlusive coil device that may “optionally contain modest amounts of iron.” (Col. 5, lines 1-2). However, there is no disclosure or suggestion in Ken that such “modest amounts of iron” in the

stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member if exposed to energy transmitted by external energy emitting element when the coil is detached from a delivery catheter and implanted at a treatment site, as required by independent claims 1, 37 and 42. Ken discloses releasing a vaso-occlusive coil in a treatment site using a well-known electrolytically severable joint (Col 6, lines 38-62), which is different than heating the already detached and implanted coil by application of energy transmitted by an energy emitting element located external to the patient. Nor is there any mention in Ken if the “optional” modest amounts of iron would be embedded in the filament versus applied as a coating, or otherwise. And, in particular, there is no mention in Ken that the coil itself contains, (or may optionally contain), any amount of iron, despite a very detailed description of what materials the coils are made from at lines 47-60 of column 4 of Ken.

Gunther discloses an induction heating device outside the body that raises the temperature of living cells that immediately surround a metallic implant in a patient's body causing shrinkage, slowing or stopping cell generation in the body (Col. 3, lines 1-7). As stated in Gunther *“the goal of the inductive heating is to raise the temperature of the cells surrounding a stent matrix so that the cells will shrink and cell generation will slow.”* (Col. 3, lines 41-43). Even if Gunther may be properly combined with Ken, such combination would not teach or suggest that the coil of Ken would be made of a material that acts as a heating member (Gunther) due to the “modest amounts of iron” in Ken.

Wallace discloses a vaso-occlusive device comprising an inner core covered with a polymeric fiber, wherein the polymeric fiber covering may be used as a carrier for bioactive molecules (Col 12, lines 4-14). As stated above, even if Ken is combined with Gunther,

and further combined with Wallace, Ken “modest amounts of iron” would not cause the stretch-resisting filament of Ken to act as a heating member if exposed to energy transmitted by external energy emitting element of Gunther, and therefore, there is no reason to continue heating the device of Ken after the coil is detached, as recited in independent claims 1, 37, and 42, **because there is no disclosure in Wallace that the bioactive agent carried by its device of Wallace is released or activated by heat.**

Also, as demonstrated above, neither Gunther nor Wallace may be properly combined with Ken to result in the invention recited in claims 1, 37 and 42, and there is no reason other than hindsight in view of the present application to further combine them with Engelson. Engelson discloses a light-emitting device that “*has been introduced into the region just outside the mouth of the aneurysm*” (Col. 8, lines 48-51) in order to reform polymers to adhere to each other and stabilize a vaso-occlusive device. There is no disclosure or suggestion in Engelson that an energy emitting device located outside the body would heat a vaso-occlusive device to release, activate bioactive agents after the device is implanted in the body. Instead, Engelson discloses a light emitting device located inside of a patient to stabilize the occlusion device.

A combination of these four cited references will not render a device having a first material, wherein if the device is detached from a delivery catheter and implanted at a treatment site, may be heated by application of energy transmitted by an energy emitting element located external to the patient, and a bioactive agent (claims 1 and 37) or second material (claim 42) which, if the device is detached from a delivery catheter and implanted at a treatment site, is released (claim 1) or activated (claim 37) or partially melt or fuse

together (claim 42) from the device upon heating the device by application of energy transmitted by said external energy emitting element.

The Supreme Court addressing the issue of obviousness in KSR International vs. Teleflex Inc., 550 U.S. ____ (2007), stated: “A patent composed of several elements is not proven obvious merely by demonstrating that each element was, independently, known in the prior art...it can be important to identified a reason that would have prompted a person of ordinary skill in the relevant field to combined the elements in the way the claimed new invention does”

There is no reason, and the office action fails to point out any, that would have prompted a person skilled in the art at the time of filing the present application, to combine the elements of the four cited references in the way claims 1, 37 and 42 do. Applicant does not concede that there is a reason to modify these references, but even if a person skilled in the art would consider modifying the device of Ken, in view of Gunther, in further view of Wallace, and in still in further view of Engelson, the resulting device would be of an occlusion coil having modest amount of iron (Ken), that may or may not be capable of acting as a heating member when exposed to energy transmitted by an energy emitting element located external to the patient to raise the temperature of the cells surrounding the coil to shrink and slow cell generation (Gunther), having an inner core covered with a polymeric fiber, wherein the polymeric fiber covering may be used as a carrier for bioactive molecules (Wallace), and using a light-emitting device in order to reform polymers to adhere to each other and stabilize a vaso-occlusive device (Engelson). Again, the combination of the four cited references would not render the results of all the claims limitations of independent claims 1, 37, and 42 of the present application.

For at least these reasons, Applicant respectfully submits that independent claims 1, 37 and 42, as well as claims 2-3, 6-8, 10-13, 18, 19, 25 and 38-41 which depend therefrom, are allowed over the 4-way combination of Ken, Gunther, Wallace, and Engelson, and requests withdrawal of the §103 claim rejections.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that all pending claims are allowable over the cited references. Accordingly, a notice of allowance is earnestly solicited. If the Examiner believes that a further telephone interview could expedite resolution of any remaining issues, he is welcome to call the undersigned at the below-listed number.

Respectfully submitted,
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